UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,355	03/15/2004	Thomas S. Wilson	IL-11176	3229

24981 7590 08/18/2009

Lawrence Livermore National Security, LLC
LAWRENCE LIVERMORE NATIONAL LABORATORY
PO BOX 808, L-703
LIVERMORE, CA 94551-0808

EXAMINER	
SONNETT, KATHLEEN C	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/801,355
Filing Date: March 15, 2004
Appellant(s): WILSON ET AL.

Eddie E. Scott
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/9/2008 appealing from the Office action mailed 10/17/2007.

(1) Real Party in Interest

A statement identifying by name the real party of interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,192,301	Kamiya et al.	3-1993
6,034,149	Bleys et al.	3-2000
2002/0095169	Maitland et al.	7-2002
5,634,936	Linden et al.	6-1997

5,207,709	Picha	5-1993
2002/0165582	Porter	11-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 6-15, 21-23, 25-37, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maitland et al. (2002/0095169; "Maitland") in view of Bleys et al. (US 6,034,149; "Bleys"). Maitland discloses an apparatus for occluding a physical anomaly comprising a shape memory polymer for positioning in the interior of the physical anomaly and a system for providing the shape memory polymer with a primary shape for occluding the physical anomaly and a secondary shape for being positioned in interior of the physical anomaly (see abstract). The apparatus also comprises a delivery system (30 and 32 or 12) capable of delivering the shape memory material body into the interior of the physical anomaly. Maitland fails to disclose that the shape memory material body comprises a shape memory polymer foam.

Foams are well known in the art for forming occlusions or sealing holes in the body to ensure that liquid cannot escape and are an obvious, known alternative form for occlusive materials. Furthermore, Bleys discloses foam that has shape memory properties, is flexible, and has a minimum amount of leachable substances, which makes the foam especially useful in medical applications (column 6, lines 46-51). It would have been obvious to one of ordinary skill

in the art to modify the device of Maitland to choose the shape memory foam of Bleys for the shape memory material body because foams are well known in the medical art for use in occluding and sealing holes in the body and the foam of Bleys includes shape memory characteristics while having improved biocompatibility from other foams because of its minimum amount of leachable substances (column 6, lines 46-51).

Regarding claims 3, 4, and 25, the shape memory foam taught by Bleys is polyurethane open cell foam. Bleys discloses that the compressed shape size is at most 60% of the expanded shape size. At most 60% percent means Bleys teaches any value less than 60%. For example, if the compressed shape size is about 33% of the expanded shape size, then the foam expands by about 200% (*200% increase*) to go from the compressed shape to the expanded shape.

Regarding claims 6 and 26, the shape memory foam has a light absorbing dye (paragraph 75 of Maitland).

Regarding claims 7, 27-29, and 33, the apparatus includes a delivery catheter (30) and a guide wire (32). The shape memory material is at the end of the guide wire.

Regarding claims 12, 13, 34, and 35, Maitland discloses a system for providing the shape memory material with a primary and secondary shape comprising a system for optical heating using optic fibers to transport light (laser) energy to the shape memory material body through the optical fiber (paragraphs 59 and 62).

Regarding claims 14 and 36, the optical fiber may be multimode (paragraph 61 of Maitland).

Regarding claims 15 and 37, the shape memory material comprises a light absorbing material (paragraph 59 of Maitland).

Regarding claims 21 and 43, the shape memory material has a primary shape that is larger than a secondary shape (figures 1, 2 of Maitland).

Regarding claims 11 and 33, modified Maitland discloses a shape memory polymer foam connected at the end of the guidewire (see fig. 7).

Regarding claims 8-10 and 30-32, Maitland discloses a system for providing the shape memory body with a primary and secondary shape comprising electromagnetic energy delivered optically (which is a form of radiation) (paragraph 57).

Claims 1, 3, 7, 21-23, 25, 27-29, 43-45, 47, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. (U.S. 5,192,301; "Kamiya") in view of Bleys. Kamiya discloses an apparatus for occluding a physical anomaly comprising a shape memory polymer for positioning in the interior of the physical anomaly and a system for providing the shape memory polymer with a primary shape for occluding the physical anomaly and a secondary shape for being positioned in interior of the physical anomaly (see abstract). The apparatus also comprises a delivery system (12 and 13) capable of delivering the shape memory material body into the interior of the physical anomaly. Kamiya fails to disclose that the shape memory material body comprises a shape memory polymer foam.

Foams are well known in the art for forming occlusions or sealing holes in the body to ensure that liquid cannot escape. Bleys discloses foam that has shape memory properties, is flexible, and has a minimum amount of leachable substances, which makes the foam especially useful in medical applications. It would have been obvious to one of ordinary skill in the art to modify the device of Kamiya to choose the shape memory foam of Bleys for the shape memory material body because of its biocompatibility (column 6 lines 45-51).

Regarding claims 3, 4, and 25, the shape memory foam taught by Bleys is polyurethane open cell foam. Bleys discloses that the compressed shape size is at most 60% of the

expanded shape size. At most 60% percent means Bleys teaches any value less than 60%. For example, if the compressed shape size is about 33% of the expanded shape size, then the foam expands by about 200% to go from the compressed shape to the expanded shape.

Regarding claims 7, 27-29, and 49, the apparatus includes delivery catheter (22) and guidewire (23). The shape memory material is at the end of the guide wire (figure 27 of Kamiya).

Regarding claims 21 and 43, the shape memory material has a primary shape that is larger than a secondary shape (Kamiya abstract). This is capable of occluding an anomaly.

Regarding claims 45 and 47, Kamiya in view of Bleys discloses a method of occluding a physical anomaly, the physical anomaly having an interior comprising the steps of providing a shape memory material body comprising a shape memory polymer foam with a secondary shape for being positioned in the interior of a physical anomaly, positioning the body in the anomaly when in its secondary shape, and causing the body to change to a larger primary shape for occlusion (Kamiya abstract). A catheter is used to position the shape memory body in the interior of the anomaly in its secondary shape (see column 7 lines 66-column 8 lines 30).

Claims 2 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maitland in view of Bleys as applied to claims 1 and 23, and further in view of Picha (US 5,207,709). Maitland in view of Bleys discloses the invention substantially as stated above including that the polymer foam has an open cell foam structure, but fails to expressly disclose the pore size.

However, Picha teaches that a pore size of 10 to 50 microns is advantageous on implantable foam because it induces blood vessel proximity and neovascularization of the implant (column 8, lines 41-46). It would have been obvious to size the open cells of the shape memory foam of Maitland in view of Bleys so that the pores are between 10 and 50 microns since Picha teaches that such pore sizes allows tissue ingrowth.

Claims 2, 24, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya in view of Bleys as applied to claims 1, 23, and 45 above, and further in view of Picha. Kamiya in view of Bleys discloses the invention substantially as stated above including that the polymer foam has an open cell foam structure, but fails to expressly disclose the pore size. However, Picha teaches that a pore size of 10 to 50 microns is advantageous on implantable foam because it induces blood vessel proximity and neovascularization of the implant. It would have been obvious to size the open cells of the shape memory foam of Kamiya in view of Bleys so that the pores are between 10 and 50 microns since Picha teaches that such pore sizes allows tissue ingrowth.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya in view of Bleys as applied to claim 1 above, and further in view of Linden et al. (US 5,634,936; "Linden"). Kamiya in view of Bleys discloses the invention substantially as stated above including that the shape memory polymer is an open-celled polyurethane foam but fails to disclose the foam being a ten percent solution in dimethyl sulfoxide (DMSO).

However, Linden teaches using DMSO as a solvent with a foam used to occlude a hole in tissue. Solvents such as DMSO can be used to keep the foam soft prior to hardening it once it has been deployed within a tissue defect. This hardening can be affected to changing the solution or by cooperative effects between the patient's blood and the foam (column 6 lines 30-45). It would have been obvious to one skilled in the art to modify the device of Kamiya to include dissolving the polymer foam within solution of DMSO since Linden teaches that such solvents paired with foams are well known and can be used to keep the foam soft prior to deployment. Regarding the claimed 10 percent solution, it has been held that discovering an optimum value of a result effective variable, in this case the amount of polymer dissolved in the

DMSO, involves only routine skill in the art (*In re Boesch,* 617 F.2d 272, 205 USPO 215 (CCPA 1980)).

Claims 17-20 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya or Maitland, in view of Bleys as discussed above and further in view of Porter (US 2002/0165582). Kamiya and Maitland in view of Bleys both disclose the invention substantially as stated above, but fail to disclose that the system for providing the shape memory material with two different shapes comprises microparticles or nanoparticles that can selectively absorb RF radiation converting it to heat.

However, Porter discloses that it is old and well known to provide microparticles in a substance used to fill any site in the human body (par. 11, 18, and 85). These particles selectively absorb RF radiation, converting it to heat. The shape memory polymer of Maitland is heated to cause the shape memory polymer to change shape and providing the microparticles of Porter would provide an advantageous means of heating because the small magnetic particles are a point heat source and do not cause significant tissue damage around the implantation site (par. 82 of Porter). Kamiya is silent regarding how the shape memory body is heated and the disclosure of Porter teaches an appropriate method to achieve such heating of the device. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Maitland or Kamiya to include magnetic microparticles as made obvious by Porter in order to have a convenient point heat source and the use of a shape memory foam with a higher transition temperature.

Regarding the use of nanoparticles, applicant has not disclosed that nanoparticles are used for any particular purpose, provide any advantage or solve a particular problem as compared to the use of microparticles. Furthermore, it would appear to one of ordinary skill in the art that the instant device and modified Maitland would perform equally well with the claimed

nanoparticles or the microparticles as taught by Porter. Therefore, it would be prima facie obvious to use the claimed nanoparticles instead of the microparticles because they are considered an obvious design choice that fails to patentably distinguish over the prior art of Maitland in view of Porter.

Claims 48 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya in view of Bleys as applied to claim 45 above and further in view of Maitland. Kamiya discloses the method substantially as stated above, but fails to disclose using a laser and optical fiber to transmit laser light through the optical fiber.

However, Maitland discloses that it is old and well known in the art to use optical fibers and lasers to heat a shape memory polymer such that it takes a larger primary shape. Kamiya discloses that the plug is warmed to change shape but is silent on how this is achieved and Maitland provides a heating method that does will not cause trauma to the surrounding tissue. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Kamiya to include using an optical fiber and laser to transmit laser light through the optical fiber to heat the shape memory body without causing surrounding trauma.

Claims 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya in view of Bleys as applied to claim 45 above and further in view of Porter. Kamiya discloses the method substantially as stated above, but fails to disclose providing a shape memory foam that has microparticles or nanoparticles of a material which can selectively absorb RF radiation converting it to heat.

As mentioned above, Kamiya is silent on how the shape memory body is warmed and Porter teaches the use of magnetic microparticles dispersed in a polymer that can selectively absorb RF radiation converting it to heat. These microparticles provide point sources of heat that do not cause significant tissue damage around the implantation site (par. 82). Providing

such a system in the body of Kamiya would allow the use of materials with transition temperatures further away from body temperature without damage to tissue. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Maitland or Kamiya to include magnetic microparticles as made obvious by Porter in order to have a convenient point heat source and to be able to use of a shape memory material with a higher transition temperature.

Regarding the use of nanoparticles, applicant has not disclosed that nanoparticles are used for any particular purpose, provide any advantage or solve a particular problem as compared to the use of microparticles. Furthermore, it would appear to one of ordinary skill in the art that the instant device and modified Maitland would perform equally well with the claimed nanoparticles or the microparticles as taught by Porter. Therefore, it would be prima facie obvious to use the claimed nanoparticles instead of the microparticles because they are considered an obvious design choice that fails to patentably distinguish over the prior art of Maitland in view of Porter.

Claims 16 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maitland. Maitland discloses the invention substantially as stated above including that the shape memory material body comprises a light absorbing material. Maitland fails to expressly disclose that the shape memory material comprises a light absorbing dye in an elastomeric coating. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a light absorbing elastomeric coating instead of a light absorbing material because Applicant has not disclosed that the elastomeric coating provides an advantage, is used for a particular purpose, or solves a stated problem over the use of a light absorbing material. One of ordinary skill in the art, furthermore, would have expected Maitland's material and applicant's invention, to perform equally well with either the material

taught by Maitland or the claimed coating because both perform the same function of absorbing light equally well.

Therefore, it would have been prima facie obvious to modify Maitland to obtain the invention as specified in claims 16 and 38 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Maitland.

(10) Response to Argument

In response to appellant's argument that the device of Maitland is not disclosed as being used for occluding a physical anomaly and is instead disclosed as being used for removing a clot in a vein or artery, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Maitland discloses an apparatus comprising the claimed structure of a shape memory material (13), a delivery system for delivering the shape memory material body (12), and a system for providing the shape memory material with a primary and secondary shape (paragraph 57). If the apparatus is delivered such that the shape memory material (13) is placed within a physical anomaly, such as an aneurysm, the material is capable of occluding the physical anomaly once it has been expanded to fill the anomaly. It is noted that Maitland has been used to reject apparatus claims only, wherein the device must only be capable of performing the intended function to meet the claimed limitation.

Appellant also argues that Bleys fails to make obvious the use of shape memory polymer foam for the shape memory material of Maitland. However, Bleys teaches that it is well known to use shape memory polymer foams in medical application and further discloses that the particular foam taught by Bleys is especially useful in areas where contact with a human

body is required (column 6, lines 46-51). Bleys also teaches that the foams can be used to control drug release which is also desirable in many medical applications (column 6, line 55). The foam is compressed to a smaller thickness and then expands to a second enlarged state after the compression is removed (see experiments 8-11 in table shown in columns 9 and 10). It would have been obvious to use such foam for the shape memory material of Maitland since Bleys discloses the suitability of such foam for medical applications and also teaches that foams can be used to control drug release.

Appellant also argues that it would not have been obvious to use the foam of Bleys for the shape memory material (11) of Kamiya because the shape memory material of Kamiya includes flanges which cannot be made of foam. It is unclear why foam cannot be fashioned into a flange in a similar manner as any other shape memory polymer material. Furthermore, the embodiment of Kamiya shown in figure 26 for example does not include a flange and therefore the shape memory material need not include flanges in order to occlude an anomaly. Appellant also argues that the shape memory foam taught by Bleys cannot support a narrow hole through which a guide wire is passed. This is not found persuasive since the hole is supported by the guide wire within it. In other words, the foam can be applied around a guidewire. Alternatively, the guide wire can be pushed through a formerly solid plug of foam.

Appellant argues that the examiner provides no explanation of how or why Maitland or Kamiya would be combined with Bleys. However, the rejections presented above in the same manner as in the final office action mailed 10/17/2007 include that it would have been obvious to one skilled in the art to employ the shape memory foam taught by Bleys as the shape memory material in the devices of Maitland and Kamiya because Bleys discloses that shape memory foam is useful in medical applications dues to its low amount of leachable substances. Such a modification can be considered a simple substitution of one known shape memory material for

another known shape memory material with a reasonable expectation of predictable results due to Bleys' disclosure of the foam being useful in medical applications. Bleys further discloses that foams can be used for a drug release product which provides the obvious advantage of drug delivery at the anomaly site.

Regarding the combination of Maitland in view of Bleys and Picha, Appellant argues that the final rejection does not provide an explanation of how or why the Maitland, Bleys, and Picha references would be combined. However, the rejection includes that it would have been obvious to size the open cells of the shape memory foam of Maitland in view of Bleys so that the pores are between 10 and 50 microns as taught by Picha because this pore size induces blood vessel proximity and neovascularization of the implant (column 8, lines 41-46). Picha similarly makes obvious the claimed pore sizes in the foam of Kamiya in view of Bleys in order to induce neovascularization of the shape memory material.

Appellant argues that the final rejection does not provide an explanation of how or why the Maitland, Bleys, and Linden would be combined. Appellant similarly argues that the examiner does not provide motivation for the combination of Kamiya, Bleys, and Linden. However, these rejections include that Linden teaches using DMSO as a solvent with a foam used to occlude a hole in tissue. Solvents such as DMSO can be used to keep the foam soft prior to hardening it once it has been deployed within a tissue defect (column 6 lines 30-45). This hardening can be affected by changing the solution or by cooperative effects between the patient's blood and the foam. It would have been obvious to one skilled in the art to modify the device of Maitland in view of Bleys, or Kamiya in view of Bleys, to include dissolving the polymer foam within solution of DMSO since Linden teaches that such solvents paired with foams are well known and can be used to keep the foam soft prior to deployment. Regarding the claimed 10 percent solution, it has been held that discovering an optimum value of a result effective

variable, in this case the amount of polymer dissolved in the DMSO, involves only routine skill in the art (*In re Boesch,* 617 F.2d 272, 205 USPO 215 (CCPA 1980)).

Appellant argues that the final rejection does not provide an explanation of how or why the Maitland, Bleys, and Porter would be combined. Appellant similarly argues that the examiner does not provide motivation for the combination of Kamiya, Bleys, and Porter. However, these rejections includes that Porter teaches the use of magnetic microparticles dispersed in a polymer that can selectively absorb RF radiation converting it to heat. These microparticles provide point sources of heat that do not cause significant tissue damage around the implantation site (par. 82). Providing such a system in the body of Kamiya of Maitland would allow the use of materials with transition temperatures further away from body temperature without risking damage to tissue. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Maitland or Kamiya to include magnetic microparticles as made obvious by Porter in order to have a convenient point heat source and to be able to use of a shape memory material with a higher transition temperature.

In response to Appellant's arguments that the examiner has not provided an explanation of how or why Kamiya in view of Bleys and Maitland would be combined in the rejection of claims 48 and 50-52, the examiner points to the rejection of these claims which clearly states that Maitland discloses that it is old and well known in the art to use optical fibers and lasers to heat a shape memory polymer such that it takes a larger primary shape (par. 59, 62). Kamiya discloses that the plug is warmed to change shape such as by saline solution and Maitland provides a heating method that does will not cause trauma to the surrounding tissue. It would have been obvious to one of ordinary skill in the art to modify the method of Kamiya to include using an optical fiber and laser to transmit laser light through the optical fiber to heat the shape memory body without causing surrounding trauma.

Regarding claims 16 and 38, the examiner maintains that coating the material with a light absorbing elastomeric coating is an obvious design consideration. Maitland discloses including a light absorbing material in the polymer but does not expressly disclose including the light absorbing material as a coating. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a light absorbing elastomeric coating instead of a light absorbing material because Appellant has not disclosed that the elastomeric coating provides an advantage, is used for a particular purpose, or solves a stated problem over the use of a light absorbing material located within the polymer material. One of ordinary skill in the art, furthermore, would have expected Maitland's material and applicant's invention, to perform equally well with either the material taught by Maitland or the claimed coating because both perform the same function of absorbing light equally well. Therefore, it would have been prima facie obvious to modify Maitland to obtain the invention as specified in claims 16 and 38 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Maitland.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Kathleen Sonnett
/Kathleen Sonnett/
Examiner, Art Unit 3731

Conferees:

Anhtuan Nguyen
/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
8/15/09

/Tom Hughes/
TQAS, TC 3700